

Support for Claim 95 is found, for example, on page 13, lines 1–3; page 17, lines 19–22; page 15, lines 5–6; page 34, lines 1–2; page 14, lines 14–15; and page 34, lines 5–8 of the specification as originally filed.

Independent Claim 96 is directed to a syringe assembly comprising another combination of structural features of the subject invention, including elements of the syringe body, retraction mechanism and plunger that are otherwise recited in the foregoing claims and well supported, for example, by FIGS. 1-3 and portions of the specification as noted above.

Response to Restriction Requirement

Applicant also responds to the restriction requirement dated December 10, 2001 in which the Examiner indicated that the application contains claims directed to a number of patentably distinct species of the claimed invention. Applicant hereby provisionally elects claims readable on the invention disclosed in the figures of Species I for examination. Applicant believes that all of Claims 29–96 as presented herein are readable on the species of FIGS. 1–3. Many of those claims are also believed to read on the invention as disclosed in relation to FIGS. 4A, 4B, 9, 11 and 12.

Dependent claims 35, 43 and 51 are cancelled herein because their subject matter has been incorporated into independent claims 29, 37 and 45, respectively.

A marked-up copy of the claim amendments and the fee to cover the additional claims accompanies this response. A three month extension of the response period is respectfully requested and payment of the fee required for a small entity under 37 C.F.R. 1.17(a)(1) also accompanies this response, together with the fee required for the additional claims. Please charge any additional fee that may be required or credit any overpayment to Deposit Account No. 12-1781 of Locke Liddell & Sapp, LLP.

Respectfully submitted,



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MARKED-UP AMENDED CLAIMS AND
NEWLY ADDED CLAIMS 56-95

The following are amended claims:

29. (Amended) A [retractable] syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion containing a retraction mechanism having a retractable needle and a continuous retaining member configured for operation by forward movement of a plunger, and a back end portion having an opening;

the continuous retaining member having one outside mating surface making a seal for a variable fluid chamber in the barrel;

a plunger having a front end portion comprising a head [and], a supporting surface on the plunger front end portion having a plunger seal element fixed on the supporting surface, and a back end portion with an end cap;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and

the retractable needle retraction mechanism being released for retraction when the plunger is moved forward to release the continuous retaining member, without contact between the plunger seal element and the continuous retaining member and without relative movement between the plunger seal element and its supporting surface;

the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction.

Please cancel claim 35 without prejudice.

36. (Amended) The assembly of claim [35] 29 wherein the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, thereby stopping the plunger from further [forward] movement and preventing reuse.

37. (Amended) A [retractable] syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion in which a retraction mechanism is mounted, the retraction mechanism having a needle [which is retractable] and a continuous retaining member which holds the retractable needle, and a back end portion having an opening;

[the retraction mechanism being operable by forward movement of a plunger without distorting the barrel;]

a plunger having a front end portion comprising a head and a supporting surface located on the front end portion, with a plunger seal element fixed on the supporting surface, and a back end portion with an end cap, the retraction mechanism being operable by forward movement of the plunger without distorting the barrel;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; [and] whereby

forward movement of the plunger releases the needle from the continuous retaining member by applying a separating force to the continuous retaining member, without the aid of the plunger seal element and without relative movement between the plunger seal element and its supporting surface;

the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction.

Please cancel claim 43 without prejudice.

44. (Amended) The assembly of claim [43] 37 wherein the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, thereby stopping the plunger from further [forward] movement and preventing reuse.

45. (Amended) A [retractable] syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion in which a retraction mechanism is mounted, the retraction mechanism having a

needle which is retractable, [and] a continuous retaining member which holds the needle, and a back end portion having an opening;

the continuous retaining member having one outside mating surface making a seal for a variable fluid chamber in the barrel;

a plunger having a front end portion comprising a head and a supporting surface located on the front end portion, [with] a plunger seal element fixed on the supporting surface, and a back end;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and

the retractable needle retraction mechanism being released for retraction when the plunger is moved forward to release the continuous retaining member, without the plunger seal element going beyond said one outside mating surface and without motion of the plunger seal element relative to its supporting surface;

the plunger end being receivable into the back of the hollow syringe body upon retraction.

Please cancel claim 51 without prejudice.

52. (Amended) The assembly of claim [51] 45 wherein the plunger end is lodged in the back of the hollow syringe body by pressing the plunger end to cause retraction, thereby stopping the plunger from further forward movement and preventing reuse.

53. (Amended) A [retractable] syringe assembly [designed for one use, comprising:

a hollow syringe body comprising a barrel having a front end portion containing a retraction mechanism] having a retractable needle and [continuous retaining member configured for operation by forward movement of a plunger;

a biasing element mounted in the front of the barrel;

a plunger having a front end portion comprising a head and a supporting surface on the front end portion having a plunger seal element fixed on the supporting surface; and

where the front of the barrel has an inwardly sloping wall continuously sloping to the point of contact with the continuous retaining member] a front end

portion with an elongate biasing element and a one piece needle holder extending through the biasing element, a portion of the needle holder protruding forwardly beyond all other structural elements of the assembly except the needle.

54. (Amended) A [retractable] syringe assembly having a retractable needle and designed for one-time use, comprising:

a front end retraction mechanism [and] having a retractable needle [including], a needle holder, a biasing element and a continuous retaining member;

a plunger having a front end portion comprising a head and a supporting surface on the front end portion having a plunger seal element fixed on the supporting surface;

a rigid plunger seal element stop surface which acts as a plunger seal element stop; [and]

wherein the needle holder has a front portion extending forwardly beyond the biasing element; and

[where] wherein the retraction mechanism is operated by forward movement of the plunger to release the retractable needle for retraction while the plunger seal element remains fixed to its supporting surface.

55. (Amended) The syringe assembly of claim 54 wherein the plunger operates the retraction mechanism by acting on the continuous retaining member to release the retractable needle for retraction while the plunger seal element remains fixed to its supporting surface.

The following are newly added claims:

--56. A syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion containing a retraction mechanism having a retractable needle, a needle holder

and a continuous retaining member configured for operation by forward movement of a plunger;

a biasing element mounted in the front of the barrel;

a plunger having a retraction cavity and a front end portion comprising a head having a reduced inside diameter relative to the retraction cavity and a supporting surface on the front end portion with a plunger seal element fixed on the supporting surface, and an end cap opposite the front end; and

the hollow syringe body further comprising a back end portion having an opening for receiving the end cap.--

--57. The syringe assembly of claim 56 wherein the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, thereby stopping the plunger from further movement and preventing reuse.—

--58. A syringe having a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body through the second open end, a plunger having a forwardly extending plunger head insertable into the body through the second open end behind the needle retraction mechanism, and a needle extending forwardly of the first open end, wherein:

the body comprises a nose adjacent to the first opening, a barrel adjacent to the second opening, and a transition zone between the nose and barrel;

the needle retraction mechanism is grounded inside the nose and comprises an elongated needle holder and a spring;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle, a reduced diameter portion at one end of the needle holding portion, the reduced diameter portion extending forwardly through the first open end; a head at another end of the needle holding portion opposite the reduced diameter portion; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the

plunger; and a retainer member having a first annular surface slidably engaging the needle holder head and a second annular surface slidably engaging the inside wall of the body opposite the needle holder head; and

the spring is confined prior to retraction inside the nose in an annulus defined by the needle holding portion and a portion of the inside wall opposite the needle holding portion;

the plunger head has a tip aligned to abut against the retainer member and slide the retainer member longitudinally out of engagement with the needle holder head during retraction; and

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction to withdraw the needle into the body through the first opening.--

--59. The syringe of claim 58 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.--

--60. The syringe of claim 58 further comprising an annular shoulder between the needle holding portion and the reduced diameter portion, the annular shoulder abutting against the inside wall proximal to the first open end to ground the elongated needle holder inside the nose.--

--61. The syringe of claim 58 wherein the tip of the plunger head defines a third opening into the retraction cavity.--

--62. The syringe of claim 61 wherein a resilient dislodgeable stopper is positioned in the third opening.--

--63. The syringe of claim 62 wherein a front portion of the dislodgeable stopper extends forwardly of the tip.--

--64. The syringe of claim 58 wherein the plunger head further comprises a slidable seal contacting the inside wall of the barrel.--

--65. The syringe of claim 64 wherein the seal is mounted in a fixed axial position on the plunger.--

--66. The syringe of claim 58 wherein the plunger further comprises an end cap opposite the head.--

- 67. The syringe of claim 66 wherein the end cap has a fourth opening.--
- 68. The syringe of claim 67 wherein a plug is inserted into the fourth opening.--
- 69. The syringe of claim 68 wherein the barrel comprises a collar adjacent to the second opening, and the end cap fits closely inside the collar when the plunger is depressed during retraction.--
- 70. The syringe of claim 69 wherein the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel.--
- 71. The syringe of claim 58 comprising a one-piece barrel.--
- 72. The syringe of claim 58 wherein the retainer member is positioned at the most constricted portion of the transition zone where the nose begins.--
- 73. The syringe of claim 58 wherein the retainer member engages the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the spring when the spring is compressed.--
- 74. The syringe of claim 58 wherein the nose comprises an annular space between the inside wall and the spring into which the retainer member is forced upon separation from the needle holder head by the plunger tip during retraction.--
- 75. The syringe of claim 58 wherein the needle is inserted into the reduced diameter portion of the elongated needle holder extending forwardly of the body and is attached to the elongated needle holder.--
- 76. The syringe of claim 58 wherein the inside wall of the nose functions as a spring guide during compression of the spring.--
- 77. The syringe of claim 58 wherein the retainer member has an outside mating surface making a seal with the inside wall.--
- 78. The syringe of claim 58 wherein at least a portion of the retraction mechanism is received into the retraction cavity during retraction.--
- 79. The retraction mechanism of claim 58 wherein the retraction mechanism is releasable by forward movement of the plunger to disengage the

retainer member from the needle holder head without contact between the plunger seal element and the retainer member.--

--80. The syringe of claim 58 wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.--

--81. A syringe having a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body, a plunger having a forwardly extending plunger head insertable into the body through the second open end, and a needle extending forwardly of the first open end, wherein:

the body comprises a nose adjacent to the first opening, a barrel adjacent to the second opening, and a transition zone between the nose and barrel;

the needle retraction mechanism is grounded inside the nose and comprises an elongated needle holder and a spring;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle and a head opposite the needle holding portion, the needle holding portion extending forwardly through the first open end; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger; and a retainer member holding the spring in compression inside the nose prior to retraction; and

a forwardly extending portion of the compressed spring is confined in an annulus defined by the needle holder and a portion of the body opposite the needle holder;

the plunger head comprises a slidable barrel seal mounted in fixed axial relation to the plunger;

the plunger head abuts against the retainer member following injection and comprises an axially slidable structure that disengages the retainer member from the head of the needle holder during retraction;

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction to withdraw the needle into the body through the first opening; and

the plunger comprises an end cap receivable into the body during retraction to prevent reuse of the syringe.--

--82. The syringe of claim 81 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.--

--83. The syringe of claim 81 wherein the barrel comprises a collar adjacent to the second opening, and the end cap fits closely inside the collar when the plunger is depressed during retraction.--

--84. The syringe of claim 81 wherein the retainer member is positioned at the most constricted portion of the transition zone where the nose begins.--

--85. The syringe of claim 81 wherein the retainer member engages the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the spring when the spring is compressed.--

--86. The syringe of claim 81 wherein the needle is inserted into the needle holder through a portion extending forwardly of the body.--

--87. The syringe of claim 86 wherein the needle is attached to the needle holder.--

--88. The syringe of claim 81 comprising a one-piece body.--

--89. The syringe of claim 81 wherein the inside wall of the nose functions as a spring guide during compression of the spring.--

--90. The syringe of claim 81 wherein the retainer member has an outside mating surface making a seal with the inside wall.--

--91. The syringe of claim 81 wherein at least a portion of the retraction mechanism is received into the retraction cavity during retraction.--

--92. The syringe of claim 81 wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.--

--93. The syringe of claim 83 wherein the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel.--

--94. The syringe of claim 81 wherein the plunger comprises an element that extends forwardly of the plunger seal to initiate retraction.--

--95. A needle retraction mechanism for a syringe, the mechanism comprising:

a hollow housing having first and second open ends;

a spring and needle holder insertable into the housing through the second open end and grounded inside the housing with a portion of the needle holder extending forwardly through the first open end, the needle holder providing an interior guide and the hollow housing providing an exterior guide for the spring during compression; and

a continuous retainer member disposed within the housing, the retainer member cooperating with the needle holder to maintain the spring in compression prior to retraction.—

--96. A syringe assembly having a hollow body with an inside wall, a retractable needle, a needle retraction assembly seated inside the body and a plunger slidably engaging a portion of the inside wall,

the retraction assembly comprising a compressible spring, a needle holder and a retainer member continuously surrounding the needle holder to hold the spring in compression prior to retraction, the inside wall and needle holder cooperating as a spring guide during compression of the spring,

the plunger comprising a handle with a longitudinally extending retraction cavity having a first inside diameter and a forwardly extending tip having a second inside diameter less than the first inside diameter, the tip defining an opening through which the needle holder is receivable into the retraction cavity during retraction; a seal disposed in fixed longitudinal relation to the plunger handle and in sliding engagement with the inside wall of the body,

the body further comprising a rigid plunger seal stop surface which acts as a plunger seal stop to limit forward movement of the plunger inside the body.--